## REMARKS

This paper accompanies a Request for Continued Examination. The claim amendments and Remarks provided herein are in response to the final rejection dated October 1, 2009.

**35 USC 103(a) rejections:**

Claims 1-10:

Claims 1-10 were rejected under 35 USC 103(a) as being unpatentable over applicant's admitted prior art (AAPA) (specification pages 1-3) in view of van Muiden (EP 0662385).

The prior art referenced by Applicant in the specification is generally discussed in the incorporated-by-reference U.S. Patent No. 5,380,304. As described therein, multi-layer introducer sheaths commonly utilized in the art are generally constructed by placing an inner liner material over a mandrel, positioning a braid or a coil over the outer surface of the inner liner, and positioning an outer thermoplastic material over the braid or coil. The assembly is placed in a heat shrink enclosure, and baked in oven to cause the thermoplastic outer layer to melt and flow between the wires of the braid or coil, such that it bonds to the outer surface of the inner liner.

Generally, it is desirable to maintain the wall thickness of an introducer sheath as small as possible. In this manner, the largest possible device can be passed into a body vessel through the smallest possible entry hole. Prior art introducer sheaths are typically provided with either a coil or a braid reinforcement. Those skilled in the art recognize that these reinforcements address different considerations. That is, a braid is typically utilized to enhance the torqueability of the sheath, whereas a coil is typically utilized to enhance the kink resistance of the sheath. (paragraph [0003]).

In theory, combining these two reinforcements in a single sheath would enhance both torqueability and kink resistance. However, utilizing both reinforcements in an intermediate layer (rather than utilizing only one of them as is common in the art) requires a greater wall thickness than would be required if only a single reinforcement was utilized. Although the wall thickness of the sheath may be

increased in order to accommodate tow reinforcements, increasing the wall thickness of a sheath may preclude its use in instances when the desire for a small entry hole is paramount. In addition to the increased wall thickness that results when two reinforcements are used, the combination of the two reinforcements in a single sheath may cause the wire or monofilament layers of the respective coil and braid to interfere with each other. Interference of this type is even more likely when the reinforcements are positioned in close proximity to each other in an attempt to minimize the increase in wall thickness of the sheath to the extent possible. When this occurs, the resulting device may have neither good torqueability nor good kink resistance. (paragraph [0005]).

The present application addresses the problems of providing a sheath having both a coil (for enhanced resistance to kinking) and a braid reinforcement (for enhanced torqueability), and yet maintaining the wall of the sheath as thin as possible. Neither of the cited references teaches or suggest such a combination.

Claim 1 has been amended as shown hereinabove. Claims 3, 5, and 9 have been canceled. As amended, claim 1 is directed to a method of manufacturing an introducer sheath. A coil is positioned over a mandrel. A first polymeric sleeve is positioned over the coil and the mandrel, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along an outer surface of the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch extending in a generally opposite direction from a pitch of the first striped extrusion. A heat shrink tube is positioned over an assembly comprising the mandrel, coil, and first and second sleeves. The assembly is heated to a temperature sufficient to cause the heat shrink material to shrink, such that the first and second polymeric sleeves melt together to form a tubular polymeric sheath body enveloping the coil, wherein the second striped extrusion is superposed over the first striped extrusion in the sheath body to define a generally braid-like configuration therein, said braid-like configuration disposed radially outwardly from the coil.

According to the Examiner, AAPA teaches positioning a sleeve over a mandrel and heating the mandrel. However, the Examiner has acknowledged that AAPA does not teach multiple sleeves with helical stripes. As such, the feature of incorporating a braid into a sheath in this manner is not derivable from AAPA.

Van Muiden was cited for allegedly teaching a method wherein a first sleeve with a striped helical pattern was positioned over a mandrel, and a second sleeve with a striped helical pattern was positioned over the first sleeve to define a braid-like configuration. According to the portions of van Muiden referenced in support of the rejection, an extrusion profile 30 is made up of two coaxial layers 31, 32, each having a number of extruded helically shaped bands of material. The bands of material 33 in the outermost layer 31 are running in the opposite direction to the helically shaped bands of material 34 in the innermost layer 32. Upon extrusion, a bond can be formed between the two layers with the helically shaped layers of material formed inside.

However, as shown in Fig. 4 of van Muiden, the sheath maintains the integrity of the separate layers 31, 32. Thus, even though van Muiden recognizes the trend toward ever thinner catheters (Col. 1, lines 17-20), in the cited embodiment of Fig. 4, van Muiden maintains two separate layers in order to provide his substitute for a braided reinforcement. In fact, the combination of the two layers in van Muiden is necessary to provide the effect of only a single reinforcing element, in this case a braid. No discussion is provided of a manner to combine this structure with a coiled reinforcement. Van Muiden teaches away from the desire to provide a sheath having as small a wall thickness as possible, and to provide the beneficial characteristics achievable with a braid. In fact, a sheath resulting from the claimed combination may not even be useable in some instances in which a smaller diameter sheath is required, much in the same manner as the prior art sheath having both a braid and a coil as referenced in the application.

Unlike either of the cited references, the method of claim 1 addresses the problem of providing both kink resistance and torqueability in a thin-walled sheath by positioning dual polymeric sleeves over a mandrel in the manner described above, and then heating the sleeves as described. A separate coil reinforcement is provided,

and the sleeves are melted together into an outer layer having the superposed striped extrusions to define the braided reinforcement. Neither reference teaches or suggests this step. As the Examiner noted, AAPA does not teach such multiple sleeves with helical stripes. Thus, the braid-like feature that provides torqueability to the sheath is not achievable in the low-profile sheath resulting from the prior art method. Similarly, van Muiden does not teach or suggest melting the two outer layers (31, 32) (e.g., no heat shrink step) to obtain the low profile that he refers to as a desirable feature. Rather, by maintaining two outer layers, he teaches away from the desirability of providing a sheath having as small a wall thickness as possible.

Applicant respectfully submits that the test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference, but rather, what the combined teachings of the references would have suggested to those of ordinary skill in the art. Further, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In making a prima facie determination of obviousness, the Examiner should identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Applicant respectfully submits that a prima facie case of obviousness of the present claims in view of the cited combination has not been set forth by the Examiner. Each of the references recognizes the desirability of providing a low profile sheath having enhanced torqueability and/or kink resistance; however, the references do not teach or suggest the solution to the problem arrived at by the present claims. In fact, although van Muiden includes some features in common with the claimed invention, the cited embodiment maintains dual outer sleeves in a manner that does not advance the desire of maintaining a low wall thickness. Applicant submits that no articulated reasoning with rational underpinning has been provided to support the obviousness finding, as required. Applicant further submits that it is only

after the benefit of Applicant's disclosure is gained that the features of the invention may appear to be obvious. Neither of the citations, either individually or in combination, teaches or suggests the manner of incorporating a braid-like configuration into a thin-walled sheath as claimed, nor do they teach or suggest a structure that is capable of enhanced bonding between the inner and outer layers as described.

Claims 21-30:

Claims 21-30 were rejected under 35 USC 103(a) as being unpatentable over Parker (US 5,380,304) in view of van Muiden (EP 0662385). Claims 22-30 depend from independent claim 21, and therefore include all of its limitations.

Claim 21 is directed to a method of manufacturing an introducer sheath. An inner liner is positioned over a mandrel, and a coil is positioned over the mandrel. A first polymeric sleeve is positioned over the coil, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch generally opposite a pitch of the first striped extrusion. The second sleeve is aligned over the first sleeve such that upon a melting of the sleeves the second striped extrusion is superposed over the first striped extrusion, and a generally braid-like configuration is defined thereby. A heat shrink material is positioned over an assembly comprising the mandrel, inner liner, coil, and first and second sleeves. The assembly is heated to a temperature sufficient to cause the heat shrink material to shrink, wherein the first and second sleeves melt together to form an outer tubular layer and to define the generally braid-like configuration therein, and the heat shrink material causes the outer tubular layer to bond to the inner liner through the coil turns.

The steps of this claim are generally illustrated in the figures, such as the sequence of Fig. 6. At a minimum, the cited art does not teach or suggest the feature of combining first and second sleeves having respective striped extrusions as

described over an inner liner and a coil, and melting the first and second sleeves in a heat shrink enclosure to form an outer tube (e.g., paragraphs [0029] and [0032]). In this manner, a sheath is obtained having the desirable features of 1) a thin wall; 2) enhanced kink resistance provided by the radially inner coil; and 3) enhanced torqueability provided by the braid-like arrangement of the first and second striped extrusions. Such a sheath is clearly not derivable from the prior art methods referenced by the Examiner, either individually or in combination.

As acknowledged by the Examiner, Parker does not teach the "positioning" steps of the claimed method that involve the arrangement of the two polymeric sleeves. Accordingly, Parker also cannot teach or suggest the "heating" step that causes the first and second "positioned" sleeves to melt together to form the outer tubular layer, and to define the braid-like configuration in that layer. Similarly, Parker does not teach or suggest the combination of a coil and a braid in a single sheath as claimed. Van Muiden was said to teach a two layer polymer sleeve for a catheter including striped helical patterns for defining a braid-like configuration. Van Muiden, however, does not teach or suggest the manner of achieving the braid-like action based upon the melting together of dual layers, each having a generally helical extrusion, wherein the extrusions in one layer have an oppositely-directed pitch from the extrusions in the other layer. Similarly, van Muiden does not teach or suggest the use of dual (coil + braid) reinforcements.

Applicant respectfully submits that the combined disclosures of the cited references fall far short of teaching or suggesting the claimed method. For example, the claimed method provides a sheath having dual reinforcements. Neither reference suggests this feature, nor is it readily derivable from them. There is no basis, other than hindsight, for combining these two references in a manner to construct a dual reinforcement sheath, since no such teaching or suggestion is provided in either reference.

The general method for constructing a coil-reinforced sheath described in Parker is not particularly well-suited for construction of sheaths having dual reinforcements, such as the sheath manufactured by the method of claim 21. As

stated in the Background of the present application (page 2, lines 11-18), utilizing both reinforcements in an intermediate layer of an otherwise conventional sheath results in a structure that may be too thick-walled for some proposed uses. In addition, the wire or monofilament layers are susceptible to interfering with each other, in which case the resulting device would have neither good torqueability nor good kink resistance.

It is significant that neither Parker nor van Muiden teaches or suggests a method in which dual reinforcing members (coil + braid) can be incorporated into his sheath. Similarly, neither reference teaches or suggests a melting step for lowering the overall profile of the layers, such that dual reinforcing members can be accommodated in a sheath that is not unreasonably thick-walled.

According to the claimed method, a sheath is formed utilizing the heat shrink technology of Parker, yet having the benefit of dual reinforcing members. Further, the sheath is formed in a manner to avoid the problems of prior art dual reinforcement sheaths discussed in the present application. The Examiner improperly combines Parker with van Muiden in order to allegedly arrive at the claim. Applicant respectfully submits that the combination is improper on numerous grounds. Neither reference suggests use of the technology taught therein in a thin-walled sheath having dual reinforcing members. Further, even if such suggestion would have been present, neither reference teaches or suggests adding a second reinforcing member by any means other than the same method used for the (first) reinforcing member already present in that particular reference. Additionally, even if a suggestion for a second reinforcing member could be found, such combination would be illogical in the context of the introducer sheath as described in the respective reference.

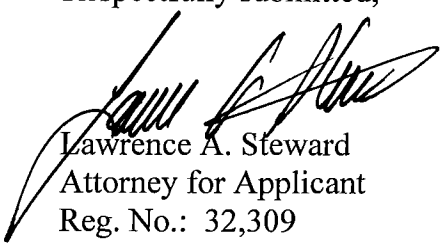
**New claims 31-33:**

New claims 31-33 have been added to the case. Claims 31 and 32 are supported, e.g., at page 11, lines 9-22 of the application. Claim 33 is supported at page 10, lines 5-6.

**Conclusion:**

Based upon the foregoing, Applicant respectfully submits that the grounds for rejection of the claims have been overcome, and that all claims 1-2, 4, 6-8, 10, and 21-33 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a timely notice of allowance. If the Examiner believes that further prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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